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APPLICATION N	0.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/626,282		07/24/2003	Joseph M. Almasian	MCA-610 US	3639
- 25182	7590	04/04/2006		EXAMINER	
MILLIPORE CORPORATION				DEAK, LESLIE R	
	290 CONCORD ROAD BILLERICA, MA 01821			ART UNIT	PAPER NUMBER
				3761	
				DATE MAILED: 04/04/2006	

Please find below and/or attached an Office communication concerning this application or proceeding.

10/626,282						
	ALMASIAN ET AL.					
Examiner	Art Unit					
Leslie R. Deak	3761					
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
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oruary 2006. action is non-final. se except for formal matters, pro parte Quayle, 1935 C.D. 11, 45						
Disposition of Claims						
4) ☐ Claim(s) 1-15 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) ☐ Claim(s) is/are allowed. 6) ☐ Claim(s) 1-15 is/are rejected. 7) ☐ Claim(s) is/are objected to. 8) ☐ Claim(s) are subject to restriction and/or election requirement.						
Application Papers						
9) The specification is objected to by the Examiner. 10) The drawing(s) filed on <u>03 February 2006</u> is/are: a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority under 35 U.S.C. § 119						
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 						
4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other:						
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DETAILED ACTION

Drawings

1. The drawings were received on 3 February 2006. These drawings are accepted.

Claim Rejections - 35 USC § 103

- 2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 3. Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,306,705 to Svensson et al.

In the specification and figures, Svensson discloses the device substantially as claimed by applicant. In particular, Svensson discloses a connection device that maintains sterility via packaging, barrier covers 10, or filters (see column 2, lines 35-44, column 4, lines 65-67, column 5, lines 57-62, column 12, lines 27-39). The device comprises a coupler 6 with housing 8 and inlet connector 6a, outlet connector 1b, passage or port 6c, o-rings 9, and stem or valve 7 movable within the port. The valve 7 is moved between various open and closed positions to allow flow through passage 6c. Svensson does not specifically disclose sealing barrier plugs, however, the inlet and outlet of the coupler may be covered by valve 3, valve 44, or filters (not labeled) to create at sterile barrier within the flow passage.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to place sterile barriers such as filters in the flow passage of the Svensson connector in order to maintain the sterility of the flow passage, also taught by Svensson.

With regard to applicant's claim drawn to the size of the openings suitable for containing a barrier plug, such variations in size are considered to be within the skill of a worker in the art. See MPEP 2144.04.

With regard to applicant's claim drawn to the motion of the port, such a limitation is a recitation of the intended use of the device. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. See MPEP 2114.

Response to Arguments

- 4. Applicant's amendment filed 3 February 2006 has been entered and considered.
- 5. Applicant's arguments filed 3 February 2006 have been fully considered but they are not persuasive.
- 6. Applicant argues that Svensson does not disclose the use of filters in the disclosed valve. However, as set forth in the rejection above, Svensson does, in fact, recite the use of filters at column 12, lines 27-39.
- 7. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies

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(i.e., radial seals) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Applicant argues that the prior art fails to disclose plugs with a radial seal. However, applicant does not set forth any structural limitations that distinguish the claimed sterile barrier plug from the barrier covers 10 disclosed by Svensson.

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- 8. In response to applicant's argument that there is no motivation to arrive at the instant invention, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). In this case, Svensson teaches that maintaining sterility within the valve is important and that the inlet and outlet may be covered by filters that act in the same manner as the plugs disclosed by applicant. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute applicant's plugs for the sterile barriers disclosed by Svensson in order to maintain a sterile passage.
- 9. In response to applicant's argument that the instant invention comprises a stem that is capable of linear movement, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the

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prior art in order to patentably distinguish the claimed invention from the prior art. See MPEP 2114.

10. In response to applicant's argument that the size of the openings is not within the skill of a worker in the art, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). In the instant case, variations in size are held to be obvious variations of the prior art absent any unexpected result. Therefore, the instant invention is unpatentable over the prior art.

Conclusion

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Leslie R. Deak Patent Examiner Art Unit 3761

22 March 2006

PATRICIA BIANCO PRIMARY EXAMINER